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SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER	
MOORE, WILLIAM W	
ART UNIT	**PAPER NUMBER**
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/538,197	FAGAN ET AL.	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9 December 2005 and 2 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *48-69* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction

Restriction is required under 35 U.S.C. §§ 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. In order to include all pending claims in this Requirement for Restriction, claim 54 is taken as though it had depended from claim 49, instead of the canceled claim 47 from which it now improperly depends.

Group 1, claims 48 and 67-69, drawn in part to a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, and to a composition comprising the protease.

Group 2, claim 48, drawn in part to a different product, a polynucleotide encoding a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, and to a composition comprising the polynucleotide.

Group 3, claim 48, drawn in part to a different product, a ligand, which may be a binding compound of clauses (g) and (h) of claim 48, capable of binding to a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, and to a composition comprising the ligand.

Group 4, claim 48, drawn in part to a different product, an antibody capable of binding to a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, and to a composition, including a kit, comprising the antibody.

Group 5, claim 48, drawn in part to a different product, an unspecified compound capable of increasing or decreasing the level of activity of a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, and a composition comprising the activator compound.

Group 6, claim 48, drawn in part to a different product, a non-human transgenic animal having an addition or an absence of a polynucleotide encoding a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith.

Group 7, claims 49, 54-56, and 62, drawn in part to a method of use of a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in diagnosing, or monitoring the treatment of, a cell-proliferative disorder or a cell-differentiative disorder exhibiting an altered level of expression of the protease.

Group 8, claims 49, 54-56, 62, and 64, drawn in part to a method of use of a polynucleotide encoding a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in diagnosing, or monitoring the treatment of, a cell-proliferative disorder or a cell-differentiative disorder exhibiting an altered level of expression of the protease.

Group 9, claims 49, 54-56, 62, and 64, each drawn in part to a method of use of a ligand capable of binding a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in diagnosing, or monitoring the treatment of, a cell-proliferative disorder or a cell-differentiative disorder exhibiting an altered level of expression of the protease.

Group 10, claims 49, 54-56, 62, and 64, each drawn in part to a method of use of an antibody capable of binding to a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in diagnosing, or monitoring the treatment of, a cell-proliferative disorder or a cell-differentiative disorder exhibiting an altered level of expression of the protease.

Group 11, claims 49, 54-56, 62, and 64, each drawn in part to a method of use of an unspecified compound capable of increasing or decreasing the activity of a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in diagnosing, or monitoring the treatment of, a cell-proliferative disorder or a cell-differentiative disorder exhibiting an altered level of expression of the protease.

Group 12, claims 49, 54-56, and 62, each drawn in part to a method of use of a non-human transgenic animal having an addition or an absence of a polynucleotide encoding a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in diagnosing a cell-proliferative disorder or a cell-differentiative disorder exhibiting an altered level of expression of the protease.

Group 13, claims 49, 54, 62, and 63, each drawn in part to another method of use of a polynucleotide encoding a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in detecting a disease in which trypsin is implicated.

Group 14, claims 49, 54, 62, and 63, each drawn in part to another method of use of a ligand capable of binding to a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in detecting a disease in which trypsin is implicated.

Group 15, claims 49, 54, 62, and 63, each drawn in part to another method of use of an antibody capable of binding to a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in detecting a disease in which trypsin is implicated.

Group 16, claims 49, 54, 62, and 63, each drawn in part to another method of use of an unspecified compound capable of increasing or decreasing the activity of a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in detecting a disease in which trypsin is implicated.

Group 17, claims 49, 54, 62, and 63, each drawn in part to another method of use of a non-human transgenic animal having an addition or an absence of a polynucleotide encoding a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in detecting a disease in which trypsin is implicated.

Group 18, claims 49-52 and 63, each drawn in part to another method of use of a protease having an amino acid sequence set forth in SEQ ID NO:22 and

fragments and variants thereof sharing at least 80% identity therewith, in treating a disease in which trypsin is implicated.

Group 19, claims 49-52 and 63, each drawn in part to another method of use of a polynucleotide encoding a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in treating a disease in which trypsin is implicated.

Group 20, claims 49-52 and 63, each drawn in part to another method of use of a ligand capable of binding to a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof at least 80% identity therewith, in treating a disease in which trypsin is implicated.

Group 21, claims 49-52 and 63, each drawn in part to another method of use of an antibody capable of binding to a set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in treating a disease in which trypsin is implicated.

Group 22, claims 49-52 and 63, each drawn in part to another method of use of an unspecified compound capable of increasing or decreasing the activity of a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in treating a disease in which trypsin is implicated.

Group 23, claims 49 and 53, each drawn in part to another method of use of a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in treating a disease by serving as an antagonist of the expression or activity of a polypeptide.

Group 24, claims 49 and 53, each drawn in part to another method of use of a polynucleotide encoding a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in treating a disease by serving as an antagonist of the expression or activity of an unspecified polypeptide.

Group 25, claims 49 and 53, each drawn in part to another method of use of a ligand capable of binding to a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in treating a disease by serving as an antagonist of the expression or activity of a polypeptide.

Group 26, claims 49 and 53, each drawn in part to another method of use of an antibody capable of binding to a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in treating a disease by serving as an antagonist of the expression or activity of a polypeptide.

Group 27, claims 49 and 53, each drawn in part to another method of use of an unspecified compound capable of increasing or decreasing the activity of a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in treating a disease by serving as an antagonist of the expression or activity of a polypeptide.

Group 28, claims 49, 54, 55, and 59, each drawn in part to another method of use of a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in identifying a compound effective in diagnosis of an a cell-proliferative disorder or a cell-differentiative disorder by assessing the level of expression or activity of the polypeptide.

Group 29, claims 49, 54, 55, 57, 56, 59, and 60, each drawn in part to another method of use of a polynucleotide encoding a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in identifying a compound effective in diagnosis of a cell-proliferative disorder or a cell-differentiative disorder by assessing the level of expression of the polynucleotide.

Group 30, claims 49, 54, 59, and 60, each drawn in part to another method of use of a polynucleotide encoding a protease having an amino acid sequence sharing at least 80% identity therewith, in identifying a compound effective in diagnosis of a cell-proliferative disorder or a cell-differentiative disorder by determining the presence or absence of a mutation in an amplified, transcribed, polynucleotide.

Group 31, claims 49, 54, 56, and 59, each drawn in part to another method of use of a ligand capable of binding to a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in identifying a compound effective in diagnosis of a cell-proliferative disorder or a cell-differentiative disorder by assessing the level of expression or activity of the polypeptide.

Group 32, claims 49, 54, 56, and 59, each drawn in part to another method of use of an antibody capable of binding to a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in identifying a compound effective in diagnosis of a cell-proliferative disorder or a cell-differentiative disorder by assessing the level of expression or activity of the polypeptide.

Group 33, claims 49 and 54, each drawn in part to another method of use of an unspecified compound capable of increasing or decreasing the activity of a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in identifying a compound effective in diagnosis of a cell-proliferative disorder or a cell-differentiative disorder by assessing the level of expression or activity of the polypeptide.

Group 34, claims 49 and 65, each drawn in part to another method of use of a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in selecting a compound that specifically binds thereto and is thus useful in treating or diagnosing a cell-proliferative disorder or a cell-differentiative disorder.

Group 35, claims 49 and 65, each drawn in part to another method of use of a polynucleotide encoding a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in selecting a compound that specifically binds thereto and is thus useful in treating or diagnosing a cell-proliferative disorder or a cell-differentiative disorder.

Group 36, claims 49 and 65, each drawn in part to another method of use of a ligand capable of binding to a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in selecting a compound that specifically binds to the protease and is thus useful in treating or diagnosing a cell-proliferative disorder or a cell-differentiative disorder.

Group 37, claims 49 and 65, each drawn in part to another method of use of an antibody capable of binding to a protease having an amino acid sequence set forth

in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in selecting a compound that specifically binds to the protease and is thus useful in treating or diagnosing a cell-proliferative disorder or a cell-differentiative disorder.

Group 38, claims 49 and 66, each drawn in part to another method of use of a transgenic animal having an addition or an absence of a polynucleotide encoding a protease having an amino acid sequence set forth in SEQ ID NO:22 and fragments and variants thereof sharing at least 80% identity therewith, in detecting a candidate compound.

The inventions lack unity, each from the other, because of the following reasons:

The invention of Group 1 lacks unity of invention with inventions of Groups 2-6 because both a polypeptide comprising an amino acid sequence of any of SEQ IDs NOs: 2, 4. 6, 8, 10, 12, 14, 16, 18, 20, 14, and 26 herein, and a polynucleotide comprising a nucleic acid sequence encoding such an amino acid sequences, are disclosed in the prior art, specifically in SEQ IDs NOs:131 and 132 of WO 00/53756 cited in the International Search Report for the PCT priority document of the instant application, PCT/GB03/05404, thus the invention of Group 1 cannot have a technical feature that is special; the technical feature of the invention of Group is the structure of a protease and no invention of Groups 2-6 shares a same or corresponding technical feature, thus inventions of Groups 1-6 share no same or corresponding technical feature that is special.

The invention of Group 2 lacks unity of invention with inventions of Groups 3-6 because the technical feature of a product of Group 2 is the structure of a polynucleotide which is disclosed in the prior art, therefore cannot be a special technical feature, and no invention of Groups 3-6 is disclosed to share a same or corresponding technical feature, thus inventions of Groups 2-6 cannot share a same or corresponding technical feature that is special.

The invention of Group 3 lacks unity of invention with inventions of Groups 4-6 because a ligand of Group 3 is a generic compound having no defined structure, therefore can have no technical feature that is special where no structure for even a representative ligand is disclosed, and no invention of Groups 4-6 is disclose to share a same or corresponding technical feature, thus inventions of Groups 3-6 cannot share a same or corresponding technical feature that is special.

The invention of Group 4 lacks unity of invention with inventions of Groups 5-6 because an antibody of Group 4 is a generic antibody where no variable domain structure, and no particular recognized epitope, is disclosed, therefore can have no technical feature that is special where no structure of even a representative antibody is disclosed, and no invention of Groups 5-6 is disclosed to share a same or corresponding technical feature, thus inventions of Groups 4-6 cannot share a same or corresponding technical feature that is special.

The invention of Group 5 lacks unity of invention with inventions of Group 6 because an enhancer and an antagonist of Group 5 are generic compounds having no defined structure, thus are indistinguishable on the present record and can have no technical feature that is special where no structure of even a representative enhancer or antagonist, is disclosed, and no

invention of Groups 6 is disclosed to share a same or corresponding technical feature, thus inventions of Groups 5 and 6 share no same or corresponding technical feature that is special.

The invention of Group 1 lacks unity of invention with inventions of Groups 7, 18, 23, 28, and 34 because the protease has no special technical feature where it is disclosed in the prior art, thus can share no technical feature with a method of use thereof in detection, selection, diagnosis, monitoring, or treatment of any of Groups 7, 18, 23, 28, and 34 that is special.

The inventions of Groups 7, 18, 23, 28, and 34 lack unity of invention, one with the other, because the different methods of use require different conditions, substrates, and procedural steps and because the only component required by all, the protease, has no technical feature that is special where it is disclosed in the prior art, thus the methods share no special same or corresponding technical feature, one with another.

The invention of Group 1 lacks unity of invention with inventions of Groups 8-17, 19-22, 24-27, 29-33 and 35-38 because the protease has no special technical feature where it is disclosed in the prior art, thus can share no technical feature with methods of use of structurally distinct compounds in detection, selection, diagnosis, monitoring, identification or treatment of any of Groups 8-17, 19-22, 24-27, 29-33 and 35-38 that is special.

The invention of Group 2 lacks unity of invention with inventions of Groups 8, 13, 19, 24, 29, 30, and 35 because the protease-encoding polynucleotide can have no technical feature that is special where it is disclosed in the prior art, thus can share no technical feature with a method of use thereof in detection, selection, identification, diagnosis, monitoring, or treatment of any of Groups 8, 13, 19, 24, 29, 30, and 35 that is special.

The inventions of Groups 8, 13, 19, 24, 29, 30, and 35 lack unity of invention, one with the other, because the different methods of use require different conditions, substrates, and procedural steps and because the only component required by all, the protease-encoding polynucleotide, has no technical feature that is special where it is disclosed in the prior art, thus the methods share no special same or corresponding technical feature, one with another.

The invention of Group 2 lacks unity of invention with inventions of Groups 7, 9-12, 14-18, 20-23, 25-28, 30-34, and 36-38 because the protease-encoding polynucleotide can have no technical feature that is special where it is disclosed in the prior art, thus can share no technical feature with methods of use of structurally distinct compounds in detection, selection, identification, diagnosis, monitoring, or treatment of any of Groups 7, 9-12, 14-18, 20-23, 25-28, 30-34, and 36-38 that is special.

The invention of Group 3 lacks unity of invention with inventions of Groups 9, 14, 20, 25, 31, and 36 because a generic ligand can have no technical feature that is special where no structure for even a representative ligand is disclosed, thus can share no technical feature with a method of use thereof in detection, selection, identification, diagnosis, monitoring, or treatment of any of Groups 9, 14, 20, 25, 31, and 36 that is special.

The inventions of Groups 9, 14, 20, 25, 31, and 36 lack unity of invention, one with the other, because the different methods of use require different conditions, substrates, and

procedural steps and because the only component required by all, a generic ligand, has no technical feature that is special where no structure for even a representative ligand is disclosed, thus the methods share no special same or corresponding technical feature, one with another.

The invention of Group 3 lacks unity of invention with inventions of Groups 7, 8, 10-13, 15-19, 21-24, 26-30, 32-35, 37, and 38 because a generic ligand can have no technical feature that is special where no structure for even a representative ligand is disclosed, thus can share no technical feature with methods of use of structurally distinct compounds in detection, selection, identification, diagnosis, monitoring, or treatment of any of Groups 7, 8, 10-13, 15-19, 21-24, 26-30, 32-35, 37, and 38 that is special.

The invention of Group 4 lacks unity of invention with inventions of Groups 10, 15, 21, 26, 32, and 37 because a generic antibody can have no technical feature that is special where no variable domain structure, and no particular recognized epitope, is disclosed for even a representative antibody, thus can share no technical feature with a method of use thereof in detection, selection, identification, diagnosis, monitoring, or treatment of any of Groups 10, 15, 21, 26, 32, and 37 that is special.

The inventions of Groups 10, 15, 21, 26, 32, and 37 lack unity of invention, one with the other, because the different methods of use require different conditions, substrates, and procedural steps and because the only component required by all, a generic antibody, has no technical feature that is special where no structure for even a representative antibody is disclosed, thus the methods share no special same or corresponding technical feature, one with another.

The invention of Group 4 lacks unity of invention with inventions of Groups 7-9, 11-14, 16-25, 27-31, 33-36, and 38 because a generic antibody can have no technical feature that is special where no structure for even a representative antibody is disclosed, thus can share no technical feature with methods of use of structurally distinct compounds in detection, selection, identification, diagnosis, monitoring, or treatment of any of Groups 7-9, 11-14, 16-25, 27-31, 33-36, and 38 that is special.

The invention of Group 5 lacks unity of invention with inventions of Groups 11, 16, 22, 27, and 33 because a generic enhancer, or antagonist, can have no technical feature that is special where no structure for even a representative enhancer, or agonist, is disclosed, thus can share no technical feature with a method of use thereof in detection, selection, diagnosis, or treatment of any of Groups 11, 16, 22, 27, and 33 that is special.

The inventions of Groups 11, 16, 22, 27, and 33 lack unity of invention, one with the other, because the different methods of use require different conditions, substrates, and procedural steps and because the only component required by all, a generic enhancer, or antagonist, has no technical feature that is special where no structure for even a representative enhancer, or agonist, is disclosed, thus the methods share no special same or corresponding technical feature, one with another.

The invention of Group 5 lacks unity of invention with inventions of Groups 7-10, 12-15, 17-21, 23-26, 28-32, and 34-38 because a generic enhancer, or antagonist, can have no technical feature that is special where no structure for even a representative enhancer, or agonist, is disclosed, thus can share no technical feature with methods of use of structurally distinct compounds in detection, selection, identification, diagnosis, monitoring, or treatment of any of Groups 7-10, 12-15, 17-21, 23-26, 28-32, and 34-38 that is special.

The invention of Group 6 lacks unity of invention with inventions of Groups 12, 17, and 38 because the polynucleotide required to make the transgenic animal, its only significant technical feature, has no technical feature that is special where it is disclosed in the prior art, thus can share no technical feature with a method of use thereof in diagnosis and detection of Groups 12, 17, and 38 that is special.

The inventions of Groups 12, 17, and 38 lack unity of invention, one with the other, because the different methods of use require different procedural steps and because the only component required by all, a protease-encoding polynucleotide, has no technical feature that is special where it is disclosed in the prior art, thus the methods share no special same or corresponding technical feature, one with another.

The invention of Group 6 lacks unity of invention with inventions of Groups 7-11, 13-16, and 18-37 because the polynucleotide required to make the transgenic animal, its only significant technical feature, has no technical feature that is special where it is disclosed in the prior art, thus can share no technical feature with methods of use of non-living agents in detection, selection, identification, diagnosis, monitoring, or treatment of any of Groups 7-11, 13-16, and 18-37 that is special.

Inventions of Groups 7-12 lack unity of invention, one with the other, because the different methods of diagnosis each requires a different kind of agent, or a different kind of compound, where no agent or compound has a technical feature that is special, as explained in the preceding statements, thus the methods share no special same or corresponding technical feature, one with another.

Inventions of Groups 7-12 lack unity of invention with the inventions of Groups 13-38 because the methods of diagnosis and monitoring of Groups 7-12 require different conditions and procedures than the methods of detection, treatment, identification, and selection of Groups 13-38, thus the methods of Groups 7-12 share no same or corresponding technical features with methods of Groups 13-38 that is special.

Inventions of Groups 13-17 lack unity of invention, one with the other, because the different methods of detection each requires a different kind of agent, or a different kind of compound, where no agent or compound has a technical feature that is special, as explained in the preceding statements, thus the methods share no special same or corresponding technical feature, one with another.

Inventions of Groups 13-17 lack unity of invention with the inventions of Groups 18-38 because the methods of detection of Groups 13-17 require different conditions and procedures

than the methods of detection, treatment, identification, and selection of Groups 18-38, thus the methods of Groups 13-17 share no same or corresponding technical features with methods of Groups 18-38 that is special.

Inventions of Groups 18-22 lack unity of invention, one with the other, because the different methods of treatment each requires a different kind of agent, or a different kind of compound, where no agent or compound has a technical feature that is special, as explained in the preceding statements, thus the methods share no special same or corresponding technical feature, one with another.

Inventions of Groups 18-22 lack unity of invention with the inventions of Groups 23-38 because the methods of treatment of Groups 18-22 require different conditions and procedures than the methods of detection, treatment, identification, and selection of Groups 23-38, thus the methods of Groups 18-22 share no same or corresponding technical features with methods of Groups 23-38 that is special.

Inventions of Groups 23-27 lack unity of invention, one with the other, because the different methods of treatment each requires a different kind of agent, or a different kind of compound, where no agent or compound has a technical feature that is special, as explained in the preceding statements, thus the methods share no special same or corresponding technical feature, one with another.

Inventions of Groups 23-27 lack unity of invention with the inventions of Groups 28-38 because the methods of treatment of Groups 23-27 require different conditions and procedures than the methods of detection, identification, monitoring, and selection of Groups 28-38, thus the methods of Groups 23-27 share no same or corresponding technical features with methods of Groups 28-38 that is special.

Inventions of Groups 28 and 29 lack unity of invention, one with the other, because the different methods of identification each requires a different kind of agent, or a different kind of compound, where no agent or compound has a technical feature that is special, as explained in the preceding statements, thus the methods share no special same or corresponding technical feature, one with another.

Inventions of Groups 28 and 29 lack unity of invention with the inventions of Groups 30-38 because the methods of identification of Groups 28 and 29 require different conditions and procedures than the methods of detection, monitoring, and selection of Groups 30-38, thus the methods of Groups 28 and 29 share no same or corresponding technical features with methods of Groups 30-38 that is special.

Inventions of Groups 30-33 lack unity of invention, one with the other, because the different methods of identification each requires a different kind of agent, or a different kind of compound, where no agent or compound has a technical feature that is special, as explained in the preceding statements, thus the methods share no special same or corresponding technical feature, one with another.

Inventions of Groups 30-33 lack unity of invention with the inventions of Groups 34-38 because the methods of identification of Groups 30-33 require different conditions and procedures than the methods of detection and selection of Groups 34-38, thus the methods of Groups 30-33 share no same or corresponding technical features with methods of Groups 34-38 that is special.

Inventions of Groups 34-37 lack unity of invention, one with the other, because the different methods of selection each requires a different kind of agent, or a different kind of compound, where no agent or compound has a technical feature that is special, as explained in the preceding statements, thus the methods share no special same or corresponding technical feature, one with another.

Inventions of Groups 34-37 lack unity of invention with the inventions of Group 38 because the methods of monitoring of Groups 34-37 require different conditions and procedures than the method of detection of Group 38, thus the methods of Groups 34-37 share no same or corresponding technical features with the method of Group 38 that is special.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Notice of Requirements for Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim

will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. §121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Inventorship

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr Bragdon, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

/Nashed/
Nashaat T. Nashed, Ph.D.
Primary Examiner, Art Unit 1656

William W. Moore
19 September 2007